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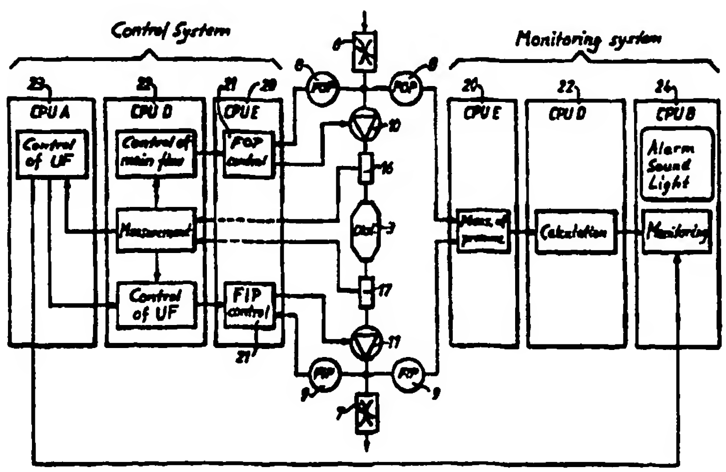

(57) Abstract

System and method for monitoring a fluid flow in a dialysis machine, comprising: constant flow means (4, 5) for feeding the dialysis fluid to a dialyzer (3) and for feeding the dialysis fluid from the dialyzer to a waste or similar. Each constant flow means comprises a restrictor (6, 7), a pump (10, 11) and a pressure sensor (8, 9) interposed therebetween, and means for controlling each pump (10, 11) for maintaining a substantially constant pressure as measured by each pressure sensor resulting in a substantially constant flow therethrough. Moreover, there are calculating means (20, 21, 22, 23, 24) for calculating dialysis fluid flow rates before and after the dialyzer (3) by means of pressure values obtained from the same pressure sensors (8, 9), according to the formula $P - P_0 = k * Q^n$ where P is a pressure on one side of the restritor, P_0 is a back pressure on the other side of the restrictor, k is a characteristic coefficient for the restrictor, Q is the fluid flow through the restrictor and n is a characteristic exponent for the restrictor.

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TITLE

SYSTEM AND METHOD FOR MONITORING A FLUID FLOW IN A DIALYSIS MACHINE

BACKGROUND OF THE INVENTION

The present invention relates to a system and method for monitoring a fluid flow in a dialysis machine. More specifically, the invention relates to a back-up system for monitoring the correct operation of dialysis fluid flow rates and/or ultrafiltration volume measurements.

BACKGROUND ART

The invention will be described below in connection with a dialysis machine, called the GAMBRO AK-100. Such a dialysis machine is described in for instance EP-B1-0 204 174 and EP-B1-0 204 260.

The dialysis machine comprises a first part for preparing, mixing and conditioning of a dialysis fluid and a second part for supplying the fluid to a dialyser and for controlling and monitoring the flow. The second part comprises two constant flow regulators positioned upstream and downstream respectively of the dialyser.

Each flow regulator comprises of a restrictor, a pressure sensor and a pump. The pressure sensor controls the pump in such a way that the pressure between the restrictor and the pump remains substantially constant. Since the inlet pressure upstream of the one throttle device and the outlet pressure downstream of the other restrictor is substantially constant, a constant pressure drop over the respective restrictor is obtained, which means a constant flow therethrough.

In hemodialysis, hemofiltration and hemodiafiltration an amount of fluid from the blood flow is separated by the filter which is used. This means that the flow downstream of the filter will be somewhat larger than the flow upstream of the filter. This ultrafiltration is adjusted by said flow regulators. There are also other ways of achieving ultrafiltration, for example by adjusting the flow regulators to the same value and taking out a separate ultrafiltration flow via a separate pump.

The remaining elements of this dialysis machine are disclosed in the aforesaid EP-B1-0 204 174, to which reference is made.

The adjustment and regulation of the dialysis machine is described in more detail in EP-B1-0 204 260. Briefly, adjustment involves that a desired ultrafiltration is set by electrical adjustment devices. Additionally, a desired flow rate is set for the dialysis fluid, for example 300 ml/minute, 500 ml/minute or 700 ml/minute. The set values are supplied to a regulating computer which calculates and/or supplies set values for pressure in the pressure sensors of the flow regulators. The pressure set values are then adjusted continually in the regulating computer depending on measured values of flow which are obtained in a separate flow measurement arrangement.

Generally, the regulating computer includes a first feed-back loop from the pressure sensors to the pumps.

Moreover, the regulating computer includes the pressure sensors in a second feed-back regulating loop maintaining the pressure at the desired value.

The first feed-back loop has a fast response and thus immediately compensates for any possible variations in the pressure, as well as any possible pressure surges in the system. The change of the set values for the pressure sensors in the second feed-back loop takes place slower.

In order to increase the safety of the system in the dialysis machine, two separate microcomputers are used, one monitoring computer and one regulating or controlling computer. Further characteristics of the adjustment arrangement are disclosed in the EP-B1-0 204 260.

The accuracy of the aforesaid system is dependent on the measurement accuracy of the flow measurement device. This flow measurement device is basically constructed as is disclosed in either of GB-B-2 003 274 or EP-B1-0 106 940.

The measurement device consists of two measuring cells, through which fluid flows pass to and from the dialyser. There is a magnetic field perpendicular to the measuring cells and platinum electrodes are in contact with the fluid flow. Voltages are generated between the electrodes due to the flow of fluid comprising ions in the magnetic field, said voltages being proportional to the flows.

Such a measuring device is however prone to operational problems, such as deposits on the measurement electrodes which can result in measurement error. This problem is described in US-A-4 585 552 and US-A-5 261 283 along with methods for avoiding or minimizing this problem.

In order to monitor the ultrafiltration, the transmembranal pressure TMP of the dialyser is used in GAMBRO AK 100. The monitoring computer checks that the transmembral pressure TMP lies within the allowed range after the pressure has stabilized. The ratio between the ultrafiltration rate and the transmembral pressure forms an ultrafiltration-coefficient, a UF-coefficient, with the help of which the actual ultrafiltration can be calculated. Such a calculation must however take account of the oncotic pressure (osmotic pressure caused by plasma proteins), the spread of the UF-coefficient for the actual type of dialysers, as well as the fact that the UF-coefficient decreases during the treatment. It can be difficult to set

an allowable range for the transmembranal pressure TMP which is sufficiently large to avoid false alarms and which is sufficiently narrow such that the corresponding range of the UF-rate will not be too large. As is clear, it can be difficult to obtain accurate measurement of the accumulated ultrafiltration volume by means of TMP, and it is only used for back-up control purpose.

DISCLOSURE OF THE INVENTION

From the above it is clear that it is desirable to further monitor the dialysis machine in order to be sure that the correct values are obtained for the flow as well as, in particular, for the flow difference for monitoring the ultrafiltration rate and volume. Such an extra monitoring can also be used in order to indicate when the flow measurement arrangement has to be cleaned, changed or taken care of in another way in order to provide the correct and confident measured values. Such monitoring can further be used in order to provide an alarm signal in the event of suspected error conditions.

From the above it is clear that such a dialysis device already comprises a throttle device and a pressure sensor which essentially detects the pressure drop over the throttle device. It is known that the pressure drop over the throttle device is approximately proportional to the square of the flow, i.e.

$$P - P_0 = k * Q^n$$

where P is a pressure on one side of the throttle device, P_0 is a back pressure on the other side of the throttle device, k is a characteristic coefficient for the throttle device, Q is the flow through the throttle device and n is the characteristic exponent of the throttle device, normally equal to about 2.0.

According to the present invention the measured value P for pressure on one side of the throttle device is used, said value already being available in the regulating computer, in order to calculate the flow through the throttle device with the help of the aforementioned equation. The flow thus calculated is compared with the measured value which is obtained from the above mentioned flow measurement device. If the difference between the calculated value and the measured value exceeds a predetermined value, suitable precautions are taken, for example generating an alarm signal.

For practical purposes it has been found that the exponent n in the above-mentioned equation can be approximated to two, i.e. a quadratic relationship exists between pressure and flow. The error of such an approximation is relatively small and can be compensated, as will be described below.

The coefficient k is dependent on the geometry of the throttle device and is determined experimentally.

The coefficient k is somewhat dependent on the temperature and can be corrected with the help of the measured temperature. The temperature value of the dialysis fluid is normally in the regulating computer.

The back pressure P_0 can be estimated, but is preferably also determined experimentally. The back pressure can also be used in order to compensate for the small variations between the real situation and the aforementioned theoretical model.

In the aforesaid dialysis machine, the pressure sensor measures pressure (P) between the throttle device and the pump, whereby it is a condition that the back pressure (P_0) on the other side of the throttle device is constant, for example equal to atmospheric pressure. If this is not the case, a differential pressure meter is preferably used which measures the pressure difference over

the throttle device. Alternatively, a second pressure sensor can of course be used to measure the back pressure.

Additional features of the invention are defined in the appended patent claims, to which reference is made.

Further objects, advantages and features of the invention will become eveident from the following description of a preferred embodiment with reference to the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a flow diagram of a known dialysis machine corresponding to the dialysis machine GAMBRO AK-100.

Fig. 2 is a block diagram which shows the logical construction of the regulating system and the monitoring system according to the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 shows a basic partial flow diagram for the GAMBRO AK-100 dialysis machine. The machine comprises a first part 1 for mixing and conditioning of the dialysis fluid and a second part 2 for supplying the fluid to a dialyser 3. Part 1 is described in detail in EP-B1-204 174 mentioned above. No further description of this part is made here.

In the second part there are two constant flow regulators 4 and 5 positioned upstream and downstream respectively of the dialyser 3 as seen in the direction of flow of the dialysis fluid.

Each flow regulator comprises a restrictor 6, 7, a pressure sensor 8, 9 as well as a pump 10, 11. The pressure sensor 8, 9 detects the pressure (P) in the conduit between the restrictor and the corresponding pump. On the other side of the respective restrictor, approximately atmospheric pressure (P_0) prevails.

A flow measuring device 12 is positioned between the flow regulators 4 and 5 for measuring the flows to and from the dialyser 3. Additionally, there are pressure sensors 14, 15 and a temperature sensor 13 for measuring the temperature of the dialysis fluid.

The flow measuring device 12 comprises two measuring cells 16, 17. Measuring cell 16 is arranged to control the set value for the pressure sensor 8 of the constant flow regulator 4 positioned upstream of the dialyzer, whilst the measurement cell 17 is arranged to control the set value for the pressure sensor 9 in the constant flow regulator 5 positioned downstream of the dialyzer.

Fig. 2 shows an electrical and logic block diagram of the regulating and monitoring system which is used in the GAMBRO AK-100 and which has been complemented in accordance with the present invention.

On the left side of Fig. 2 a conventional regulating system such as used in the GAMBRO AK-100 is shown. The above described arrangements such as the restrictor 6, the pump 10, the measuring cell 16, the dialyser 3, the measuring cell 17, the pump 11 and the restrictor 7 are shown in the middle and are positioned in the given order in the flow direction of the dialysis fluid. Additionally a first pressure sensor 8 is shown, denoted FOP, and a second pressure sensor 9, denoted FIP.

The pressure sensors 8, 9 send electrical signals to a microprocessor 20 denoted CPU E. A block 21 in the CPU E takes care of the regulation of the pump 10 and 11 respectively so that the pressure detected by the pressure sensor 8 and 9 respectively corresponds with a respective set value. The set value is calculated in a second microprocessor 22 denoted CPU D on the basis of measured signals from the measuring cells 16, 17 and in dependence on the set desired values of the main flow and ultrafiltration.

Thus, there is a first control loop for regulating the pump 10 and 11 respectively via the pressure sensor 8 and 9 respectively and the block 21. Additionally there is a second control loop from the measuring cells 16, 17 to the microprocessor 22, CPU D, which sends the set values to the block 21 for controlling the first control loop and, along with this, the respective pumps. The first control loop has a small time constant whilst the second control loop has a large time constant.

The second microprocessor 22, CPU D, calculates the accumulated ultrafiltration volume. A third microprocessor 23, CPU A, takes care of the regulation of the ultrafiltration. The calculated ultrafiltration volume is fed to a fourth microprocessor 24, CPU B, where the calculated value is compared to a set value. If the difference from the set value is too large, alarm signals are produced, such as sound and/or light signals.

According to the present invention the measurement signals from the pressure sensors 8, 9 are used additionally to calculate the flow through the throttle devices 6, 7 with the help of the aforementioned equation. The measurement signals from the pressure sensors 8, 9 are already in the microprocessor 20, CPU E. These measured values are fed to the microprocessor 22, CPU D, where the calculation of the flows through respective throttle devices 6, 7 occurs. The difference between these calculated flows is accumula-

ted and fed to the microprocessor 24, CPU B, for comparison with the value of the accumulated ultrafiltration volume calculated in the microprocessor 23, CPU A. The calculated flows can also be used for comparing with the measured signals from the measuring cells 16, 17 in order to check that these cells are working correctly.

The aforementioned equation comprises three parameters namely the exponential n, the coefficient k and the back pressure P_0.

The exponential n depends on the geometry of the restrictor device. In GAMBRO AK-100 dialysis machine a restrictor is used which consists of several radial inlet flows to a small axial channel. The channel terminates in a well rounded edge. We have found that the exponential n for such a restrictor is very close to 2. Thus n = 2 is used in accordance with the present invention. For other types of restrictor devices or throttle devices, n is approximated to particular values which can be determined experimentally. According to the invention the value of n is not changed during use.

The coefficient k is determined in advance prior to using the dialysis machine in a separate calibration step. The coefficient k_{kal} obtained in the calibration step is checked before and during dialysis but is not normally adjusted during dialysis. If the coefficient changes value during the dialysis treatment this is treated as a serious error which should be sorted out.

The back pressure P_0 constitutes a measured value of the pressure which exists on the other side of the throttle device. The back pressure can be different depending on the degree of filling of a vessel which is used in the first part of the dialysis machine, or can depend on the height of a drain where the dialysis fluid is discharged from the machine. Pressure variations can also be present for example with air build-up in the drain tube. The back pressure P_0 comprises a conglomeration of the flow resist-

ances which are present from atmospheric pressure to the restrictor and therefore includes not only the static pressure but also height differences and dynamic pressure such as flow resistances in the tubes, valve devices and other components.

The back pressure P_0 is determined and/or is measured both during the calibration step as well as during start-up of the dialysis device and with intermittently performed estimations during the dialysis treatment. The back pressure P_0 is used in order to adapt the equation so that the difference between the actual flow and the flow calculated according to the equation is minimal.

CALIBRATION

During calibration, the dialysis machine is coupled such that the dialyser is shunted and the same dialysis fluid passes through both restrictors and both measuring cells. The flow through the dialysis machine is set for two different values and the pressure readings of the pressure sensors are registered. The flow can be measured with the help of an outer measurement device for instance by measurement of the volume which is passed during a certain time, whereby the measuring cells can be calibrated at the same time. Alternatively the measured value from the measuring cells 16 and 17 can be used as a measurement of the flow. The relationship between pressure and flow is thus determined at two different measuring points. The coefficient k_{kal} and back pressure P_{0kal} are calculated according to the formula below for each restrictor by using the four obtained measured values:

$$k_{kal} = \frac{P_1 - P_2}{Q_1^2 - Q_2^2} \qquad P_{0kal} = \frac{P_2Q_1^2 - P_1Q_2^2}{Q_1^2 - Q_2^2}$$

In order to obtain high accuracy for the calculation of the coefficient k_{kal}, calibration measuring with large flow differences is required. The determination of the coefficient k_{kal} is given priority during calibration.

Additional measurements of the dialysate flow can also be carried out in order to control the calculation of the coefficient k_{kal} as well as for checking that the exponent n can be approximated to the believed value, here 2.0.

START-UP

During start-up of the dialysis machine before actual dialysis, preferably both nominal flow, such as 500 ml/min, and nominal flow minus 50 ml/minute are used. The dialyser is thereby shunted so that the same flow passes through both restrictors and both measuring cells respectively. These two flows are used in order to determine the coefficient k and the back pressure P_0. Since the difference between both flows is relatively small the determination of the coefficient k is relatively uncertain. The determination of the coefficient k is only used to check that coefficient k_{kal} lies within the given limits. Depending on which nominal flow it is intended to use, there are different sizes of restrictors in the dialysis machine. Nominal flow can be e.g. 300, 500 or 700 ml/minute. If the determined coefficient k does not lie within the given limits for any of these restrictors, an error signal is emitted. The cause can be that the flow meter and/or the restrictor requires cleaning.

The back pressure P_0 can be determined with great certainty. The obtained back pressure P_0 is compared with the calibrated pressure P_{0kal} and has to be within given limits.

The temperature and the conductivity for the dialysis machine are thereafter regulated and then an estimation is carried out.

ESTIMATION

During the dialysis process the dialyser is decoupled at regular intervals by means of the shunt arrangement. During estimation a check is made of how much the back pressure P_0 for the second restrictor 7 has changed. The interval between estimations is determined by what seems reasonable with respect to how large the total volume error can be until the next estimation, and is normally about 30 minutes. During estimation, the back pressure P_0 for the second restrictor 7 is corrected to be in accordance with the measured values from the corresponding measuring cells.

During estimation the coefficient k_{kal} can also be checked by the use of two different flows, for example nominal flow as well as nominal flow minus 50 ml/minute. Apart from this the error in the coefficient k_{kal} can, to a certain extent, be compensated by correction of the back pressure P_0.

MONITORING DURING TREATMENT

The measured values from the pressure sensors are fed continually to the regulating computer from the pressure sensors. With the help of the coefficient k_{kal} and the back pressure P_0 the flows through the restrictors can be calculated continually. Such calculations occur in the regulating computer, only at predetermined intervals depending on the calculation capacity of the regulating computer and in dependence on the desired accuracy of the monitoring of the ultrafiltration rate. The difference between the calculated flows is accumulated in order to obtain a calculated ultrafiltration volume which is compared with the accumulated ultrafiltration volume which has been calculated in a conventional manner by the regulating computer. If the difference exceeds a predetermined value, a technical error is indicated. The limit can

be set such that the volumetric difference is allowed to be larger at the end of the treatment than at the start of the treatment. Such limit can be a percentage error or absolute error.

The monitoring of the function of the ordinary measuring cells has been described above by means of using the calculated flow. It is possible to completely replace the measuring cells with flow measurement according to the present invention, whereby the calibration and/or start-up occurs for example by measuring the volume per unit of time. Monitoring can thereby occur by means of the measuring cells or with separate flow meters of the volumetric type or in other ways, such as described in Swedish Patent Application No. 94.04245-4.

As appears from the drawings, the pump of each constant flow device is positioned closer to the dialyzer than the restrictor. This is of importance, since the control feed-back loop is across the pump. The feed-back loop includes amplification means, which very carefully and rapidly counterfeits every tendence of altering the pressure between the pump and restrictor. The arrangement can be compared to a transistor connected in common emitter coupling, where the base-emitter-junction is the restrictor and the base-collector-junction is the pump. By having a large pressure drop across the restrictor, further advantages are obtained. By having the other side of the restrictor connected to a constant back-pressure, such as atmospheric pressure, further advantages are obtained.

As an alternative to using available microprocessors, a separate measuring computer especially for monitoring can be used according to the invention.

Other alternatives are the use of the same computer CPU D 22 for both regulating and monitoring in order to improve the quality of the flow measurement.

Additionally the measuring cells can of course be of a different type than those described above, for example such as those disclosed in US-A-4 827 430.

The invention has been described above with reference to the preferred embodiments of the invention shown in the drawings. It is however clear that the invention can be modified in many ways without departing from the inventive idea. Modifications which would be obvious for the skilled man are thus intended to be included within the framework of the invention. The invention is only limited by the appended claims.

CLAIMS

1. System included in a dialysis machine for measuring and/or monitoring flow rates and/or volumes of a dialysis fluid in said dialysis machine, comprising:
constant flow means (4,5) for feeding said dialysis fluid to a dialyzer (3), and for feeding said dialysis fluid from the dialyzer to a waste or similar;
each constant flow means comprising a throttle device (6,7), a pump means (10,11) and a pressure sensor (8,9) interposed therebetween;
means for controlling each pump means (10,11) for maintaining a substantially constant pressure as measured by each pressure sensor resulting in a substantially constant flow therethrough;
characterized by calculating means (20,21,22,23,24) for calculating dialysis fluid flow rates before and after the dialyzer (3) by means of pressure values obtained by said pressure sensors (8,9), according to the formula (known per se):

$$P - P_0 = k * Q^n,$$

whereby P is a pressure on one side of the throttle device, P_0 is a back pressure on the other side of the throttle device, k is a characteristic coefficient for the throttle device, Q is said fluid flow through the throttle device and n is a characteristic exponent for the throttle device.

2. System according to claim 1, inlcuding measuring means (16,17) for measuring the dialysate flow rates before and/or after the dialyzer and/or for measuring ultrafiltration rate and/or volume, **characterized** by comparison means (24) for comparing the actually measured values of said measuring means (16,17) with the corresponding values calculated by said calculation means (20-24).

3. System according to claim 1 or 2, **characterized** in that said pump means (10,11) of each constant flow means (4,5) is positioned closer to the dialyzer than said throttle means.

4. System according to claim 2 or 3, **characterized** in that said characteristic exponent n is approximated to a predetermined value, for example two.

5. System according to claim 4, **characterized** by a separate flow measurement arrangement (16,17) in said dialysis fluid flow for calibration of said characteristic coefficient k and/or said back pressure P_0.

6. System according to claim 4 or 5, **characterized** by a temperature measuring arrangement (13) for correction of said coefficient k, and/or back pressure P_0 in dependence on the temperature.

7. System according to claim 4, 5 or 6, **characterized** in that said back pressure P_0 is approximated to a constant predetermined value, for example atmospheric pressure.

8. Method for measuring and/or monitoring flow rates and/or volumes of a dialysis fluid in a dialysis machine, comprising the steps of:
feeding said dialysis fluid to a dialyzer by a first constant flow means;
feeding said dialysis fluid from the dialyzer to a waste or similar by a second constant flow means;
each constant flow means comprising a throttle device, a pump means and a pressure sensor interposed therebetween;
controlling each pump means for maintaining a substantially constant pressure as measured by each pressure sensor resulting in a substantially constant flow therethrough;
characterized by calculating dialysis fluid flow rates before and after the dialyzer (3) by means of pressure values obtained by said pressure sensors (8,9), according to the formula (known per se):

$$P - P_0 = k * Q^n,$$

whereby P is a pressure on one side of the throttle device, P_0 is a back pressure on the other side of the throttle device, k is a characteristic coefficient for the throttle device, Q is said fluid flow through the throttle device and n is a characteristic exponent for the throttle device.

9. Method according to claim 8, including the step of measuring the dialysate flow rates before and/or after the dialyzer and/or for measuring ultrafiltration rate and/or volume by measuring means, **characterized** by comparing the actually measured values with the corresponding calculated values.

10. Method according to claim 9, **characterized** by calibration of parameters in said formula by

feeding at least two different large flows through said throttle device and said measuring means,

measuring the pressure differential over said throttle device at said different flows;

measuring the flow through said throttle device at said different flows by means of said measuring device;

calculating of at least two parameters in said formula, such as said characteristic coefficient k and said back pressure P_0.

11. Method according to claim 8, 9 or 10, **characterized** by calculating accumulated ultrafiltration with the help of said separate measuring device for dialysis flow and monitoring said accumulated ultrafiltration with the help of the calculated flows through respective throttle devices.

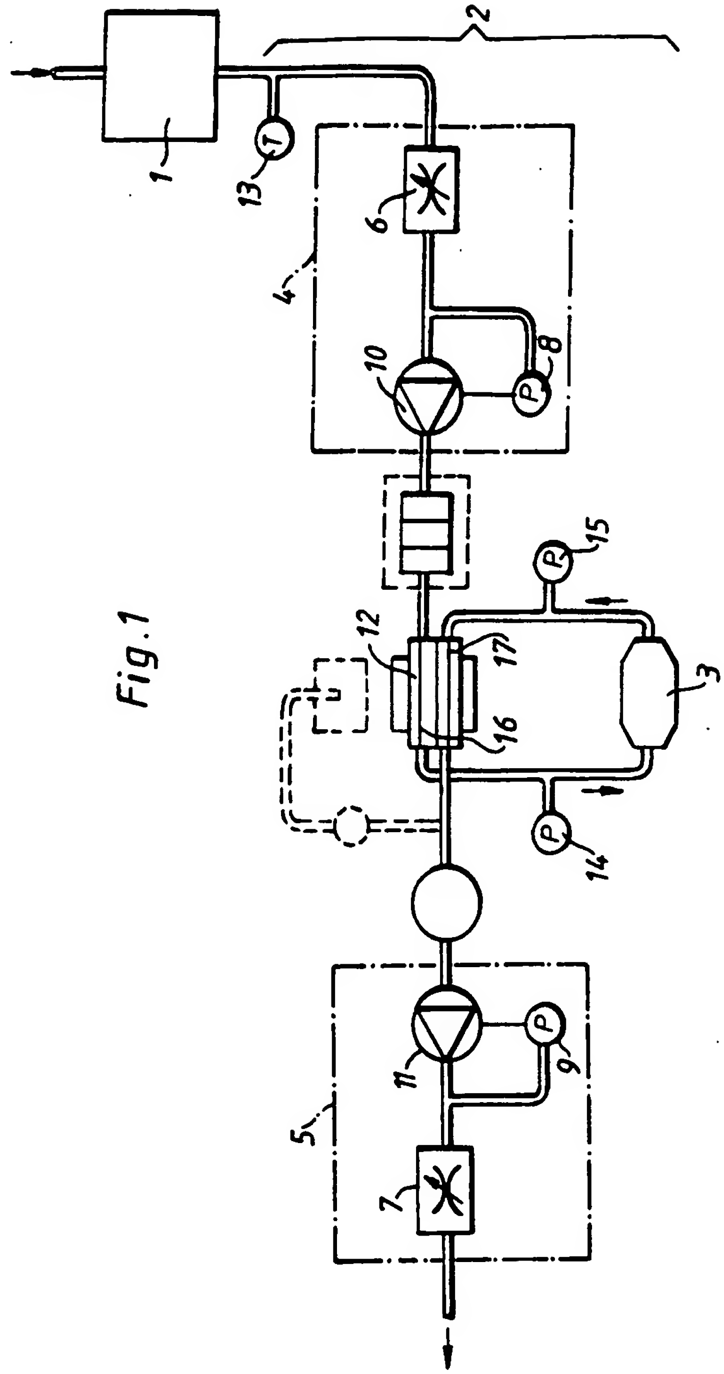
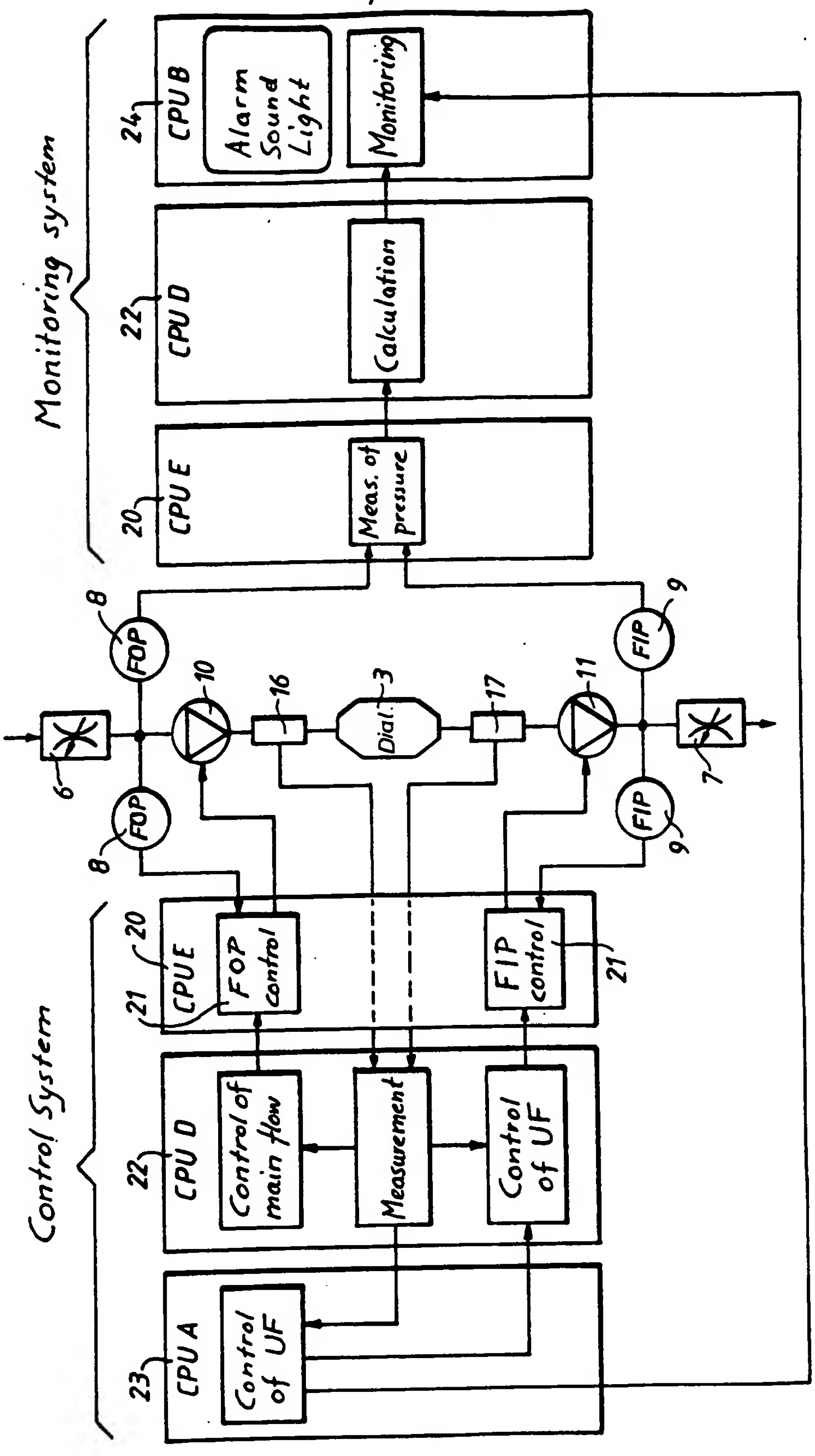


Fig.1

Fig. 2


Monitoring system
CPU B
Alarm Sound Light
Monitoring
CPU D
Calculation
CPU E
Meas. of pressure
FOP
FIP
Dial.
Control System
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FOP control
FIP control
CPU D
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Control of UF
CPU A
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00166

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: G01F 1/36, A61M 1/14, G05D 7/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: G01F, G05D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP, A1, 0565485 (EMILE EGGER & CO. AG), 13 October 1993 (13.10.93), page 2, line 39 - page 3, line 3; page 3, line 48 - line 50, figure 1, abstract --	1-11
Y	EP, A2, 0204174 (GAMBRO AB), 10 December 1986 (10.12.86), figure 1, abstract --	1-11
A	EP, A1, 0579559 (HOSPAL INDUSTRIE), 19 January 1994 (19.01.94), abstract --	1-11

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
24 May 1995	09 -06- 1995
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00166

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP, A2, 0298587 (BAXTER INTERNATIONAL INC.), 11 January 1989 (11.01.89), figure 1, abstract --	1-11
A	GB, A, 2003274 (REPGREEN LIMITED), 7 March 1979 (07.03.79), claim 1, abstract --	1-11
A	J. Phys. E: Sci. Instrum., Volume 15, 1982, T J S Brain et al, "Survey of pipeline flowmeters" page 968, column 1, line 26 - page 971, column 1, line 3 --	1-11
A	Technisches Messen tm, Volume 52, No 1, 1985, D. Meyer et al, "Erfahrungen beim Einsatz von Durchfluss- und Mengenmessern in der chemischen Industrie" page 13, column 2, line 16 - page 14, column 2, line 25 -- --------	1-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

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PCT/SE 95/00166

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP-A1-	0565485	13/10/93	NONE		
EP-A2-	0204174	10/12/86	DE-A-	3681827	14/11/91
			JP-A-	61279250	10/12/86
			SE-B,C-	447963	12/01/87
			SE-A-	8502757	05/12/86
			US-A-	4762618	09/08/88
EP-A1-	0579559	19/01/94	NONE		
EP-A2-	0298587	11/01/89	DE-D,T-	3850178	26/01/95
			ES-T-	2056923	16/10/94
			JP-A-	63308519	15/12/88
			US-A-	4827430	02/05/89
GB-A-	2003274	07/03/79	JP-C-	1491109	07/04/89
			JP-A-	54034268	13/03/79